

A<sup>7</sup>  
cancel.

23. The composition of Claim 22 wherein said cosmetic oil formulation includes one or more additives selected from the group consisting of nutrients, fragrances and sunscreens, which are soluble in the cosmetic oil formulation.

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Please add claims 25 and 26:

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25. A process for delivery of water nanocluster compositions through the outermost layer of human skin, comprising the steps of:

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preparing a water nanocluster composition comprising water nanoclusters having at least one dimension thereof being between about 0.8 and about 10 nanometers and an oil formulation in the form of a water-in-oil emulsion, and

applying said water nanocluster composition onto the outermost layer of human skin.

26. A water-in-oil emulsion composition comprised of:

(1) about 5 to 50% by weight water containing water nanoclusters having at least one dimension between about 0.8 and about 10 nanometers,

(2) about 10 to 90% by weight of an oil formulation and

(3) about 5 to 50% by weight of one or more surfactants selected from the group consisting of fatty acids, ethoxylates and alcohols.

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#### Remarks

Claims 1-24 are pending in the application. Claims 1-24 are rejected and claims 14, 16, and 22 are further objected to because of informalities. In this response, claims 4, 5, and 12-14 have been cancelled; claims 1, 3, 7, 9, 11, 16-18, 22, and 23 have been amended; and claims 25 and 26 have been added. Applicant respectfully submits that these amendments and the following Remarks remove all grounds for rejection of the application, thereby placing it in condition for allowance.

Amendment of claims:

Claims 4, 5, and 12-14 have been cancelled. Cancellation of claims 4, 5, and 12-14 is without prejudice, without intent to abandon any original claimed subject matter, and without intent to acquiesce in any rejection of record. Applicant reserves the right to file one or more continuing applications hereof containing these cancelled claims.

Claims 3, 7, 9, 16, 22, and 23 have been amended to correct obvious grammatical and/or typographical errors. Applicant respectfully submits that these corrections address and overcome the Examiner's objections to claims 16 and 22 and the rejection of claims 16 and 23 under 35 U.S.C. § 112.

Claims 1 and 11 have been amended to specify that the water nanocluster composition includes *pentagonal dodecahedral* water nanoclusters. Support for this amendment can be found in the original application, e.g., Figures 2-6; page 3, line 22 to page 4, line 16.

Claim 17 has been amended to clarify what Applicant claims as an embodiment of his invention, namely a composition comprising *surfactants that are clathrated by pentagonal dodecahedral water nanoclusters* resulting in reverse micelles of about 3 nanometers in diameter. Support for this amendment can be found in the original application, e.g., Figures 3 and 4 and page 8, lines 22-30.

Claim 18 has been amended to clarify what Applicant claims as another embodiment of his invention, namely a composition comprising *surfactants that are clathrated in the needle cavity of multi-water cluster arrays* resulting in cylindrically symmetric micelles with a large dimension of about 4 nanometers and a small dimension of about 0.8 nanometers. Support for this amendment can be found in the original application, e.g., Figures 7 and 8 and page 8, line 30 to page 9, line 6.

Claims 25 and 26 have been added to clarify what Applicant claims as yet another embodiment of his invention, namely the preparation and use of compositions that include water nanoclusters with at least one dimension *between about 0.8 and about 10 nanometers*. Support for these new claims can be found in the original application, e.g., Figures 2 and 7 and page 3, line 25 to page 4, line 16.

Applicant submits that no new matter has been presented with these amendments.

Rejection over EP Patent Appln. No. 0916621 in view of U.S. Patent No. 5,711,950 and U.S. Patent No. 4,165,385:

Claims 1-24 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over EP Patent Appln. No. 0916621 to Toshimitsu ("Toshimitsu") in view of U.S. Patent No. 5,711,950 to Lorenzen ("Lorenzen") and U.S. Patent No. 4,165,385 to Lefebvre ("Lefebvre"). These rejections are respectfully traversed; reconsideration and withdrawal is requested.

As amended, claims 1 and 11 (and claims 2, 3, 6-10, and 15-24 that depend therefrom) relate to water-in-oil emulsions that include *pentagonal dodecahedral* water nanoclusters.

As highlighted by the Examiner, Toshimitsu provides no indication of the shape or size of the "fine clustered water" used in his invention. Lorenzen discusses the preparation of "microclustered water" and alleges that the clusters include 3-15 molecules. Lorenzen teaches away from the use of larger clusters by stating that "larger clusters are believed to have a lower biomedical effect" (see column 8, lines 49-54). Lefebvre does not teach water clusters. Applicant respectfully submits that irrespective of whether one of ordinary skill in the art would have been motivated to combine these references, the combination does not teach the claimed invention. In particular since the alleged clusters of Lorenzen include up to, and no more than, 15 molecules they cannot encompass the pentagonal dodecahedral clusters that are taught and claimed by the present invention. Indeed, as highlighted in the Figures and specification of the present application, pentagonal dodecahedral clusters include 20 or 21 molecules.

Applicant would also like to point out that claims 15 and 16 specify that the water clusters are arranged as *multi-water cluster arrays* and that claims 17 and 18 specify that the water nanoclusters are associated with surfactant molecules resulting in *reverse* and *cylindrically symmetric micelles*, respectively. Applicant found no teaching in Toshimitsu, Lorenzen, or Lefebvre of multi-water cluster arrays or of micelles resulting from the interaction of water clusters and surfactants.

Since the combined teachings of Toshimitsu, Lorenzen, and Lefebvre do not include all the limitations of claims 1-3, 6-11, or 15-24, they cannot render these claims obvious. MPEP § 706.02(j). Accordingly, Applicant respectfully requests that the Examiner reconsider and

withdraw the rejection of claims 1-3, 6-11, or 15-24 (claims 4, 5, and 12-14 have been cancelled).

Applicant would also like to point out that since the combined teachings of Toshimitsu, Lorenzen, and Lefebvre do not teach the use of water nanoclusters that have at least one dimension that is between about 0.8 and 10 nanometers as recited by new claims 25 and 26, the combined references cannot render these new claims obvious.

Rejection over EP Patent Appln. No. 0916621 in view of U.S. Patent No. 5,711,950 and U.S. Patent No. 5,800,576:

Claims 1, 4-5, and 12-16 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over EP Patent Appln. No. 0916621 to Toshimitsu ("Toshimitsu") in view of U.S. Patent No. 5,711,950 to Lorenzen ("Lorenzen") and U.S. Patent No. 5,800,576 to Johnson ("Johnson"). These rejections are respectfully traversed; reconsideration and withdrawal is requested.

The Examiner relies on Johnson to teach water clusters that are of the claimed shape and size. Applicant challenges the Examiner's assertion that one of ordinary skill in the art would have been motivated to combine the teachings of Johnson with the teachings of Toshimitsu and Lorenzen. Johnson teaches the use of water clusters in *fuels* to reduce diesel-fuel combustion pollution. As the Examiner correctly points out, Johnson also mentions that water is of critical importance in biological reactions. Applicant does not dispute that water is important in biological reactions – the human body is 70% water. However, the water that is referred to by Johnson in this general context is *ordinary bulk liquid water*. There is no teaching or suggestion that the *pentagonal dodecahedral water clusters* that are described in Johnson could or should be prepared in water-in-oil emulsions of the type disclosed in the present application. Furthermore, Lorenzen specifically teaches away from the use of clusters that include more than 3-15 molecules (see column 8, lines 49-54) and hence teaches away from the use of pentagonal dodecahedral water clusters.

Applicant therefore respectfully submits that the Examiner is applying improper hindsight reconstruction by attempting to substitute the water clusters that are taught by Toshimitsu and Lorenzen with the water clusters that are taught by Johnson. Accordingly, Applicant respectfully


requests that the Examiner reconsider and withdraw the rejection of claims 1, 15, and 16 (claims 4, 5, and 12-14 have been cancelled). Applicant further submits that since the combination of references is improper it cannot be used to reject new claims 25 and 26.

### Conclusion

Based on the arguments presented above, it is submitted that the pending claims, as amended herein, are allowable over the art of record. As required, attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached page is captioned "Version with markings to show changes made". For the Examiner's convenience, also attached hereto is an Appendix showing all pending claims as amended remaining in this application. Applicant requests that, upon receipt of the present Response to Office Action, the Examiner please contact the undersigned at (617) 248-5175 so that a telephone Interview may be arranged. Applicant would also like to thank the Examiner for his thoughtful comments and careful consideration of the case.

Please charge any fees that may be required, or credit any overpayment, to our Deposit Account No. 03-1721.

Respectfully submitted,



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on 5/2/02  
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**Version with markings to show changes made**

In the claims:

Claims 4, 5, and 12-14 have been cancelled.

Claims 1, 3, 7, 9, 11, 16-18, 22, and 23 have been amended as follows:

1. A process for delivery of a water nanocluster composition[s] through the outermost layer of human skin, comprising the steps of:

preparing a water nanocluster [water-in-oil (W/O) emulsion] composition comprising pentagonal dodecahedral water nanoclusters having [with] at least one dimension thereof being less than about 10 [ten (10)] nanometers and an oil formulation in the form of a water-in-oil [W/O] emulsion, and

applying said water nanocluster composition onto [into] the outermost layer of human skin.

3. The process of Claim 2 wherein said water nanocluster composition is comprised of [surfactants comprises] about 5 to 25% by weight surfactants [of said water nanocluster composition].

7. The process of Claim 1 wherein said oil formulation is a cosmetic oil formulation.

9. The process of Claim 1 wherein said water nanoclusters in said water nanocluster composition are present together with bulk water but constitute the predominant [predominate] form of water present in said water nanocluster composition.

11. A water-in-oil [(W/O)] emulsion composition comprised of:

(1) about 5 to 50% by weight water containing pentagonal dodecahedral water nanoclusters having at least one dimension of less than about 10 nanometers,

(2) about 10 to 90% [%] by weight of an oil formulation and

(3) about 5 to 50% [%] by weight of one or more surfactants selected from the group consisting of fatty acids, ethoxylates and alcohols. [The composition of Claim 11 wherein said at least one dimension is less than about 1 nanometer.]

16. The composition of Claim 15 [11] wherein said multi-water cluster arrays are needle-like [need-like] in form, having at least one dimension less than about 1 nanometer and a second dimension greater than about 3 nanometers

17. The composition of Claim 11 wherein said surfactants are clathrated by said water nanoclusters and extend therefrom resulting in reverse micelles of about 3 nanometers in diameter [the composition is in the form of a water-in-oil nanoemulsion].

18. The composition of Claim 16 [18] wherein said surfactants are linearly clathrated in the needle cavity resulting in cylindrically symmetric micelles with a large dimension of about 4 nanometers and a small dimension of about 0.8 nanometers [said water/oil nanoemulsion is comprised of micelles containing the water clusters and surfactants, and said micelles have an average diameter of about 5 nanometers].

22. The composition of Claim 11 wherein the oil formulation is a cosmetic oil formulation [cosmeticoil] selected from the group consisting of soybean, peanut, olive, sesame and paraffin.

23. The composition of Claim 22 [23] wherein said cosmetic oil formulation includes one or more additives selected from the group consisting of nutrients, fragrances and sunscreens, which are soluble in the cosmetic oil formulation.

Claims 25 and 26 have been added.

### **Appendix – Claims pending after Amendment**

1. (Once amended) A process for delivery of a water nanocluster composition through the outermost layer of human skin, comprising the steps of:
  - preparing a water nanocluster composition comprising pentagonal dodecahedral water nanoclusters having at least one dimension thereof being less than about 10 nanometers and an oil formulation in the form of a water-in-oil emulsion, and
  - applying said water nanocluster composition onto the outermost layer of human skin.
2. The process of Claim 1 wherein said water nanocluster composition further comprises one or more surfactants selected from the group consisting of fatty acids, ethoxylates and alcohols.
3. (Once amended) The process of Claim 2 wherein said water nanocluster composition is comprised of about 5 to 25% by weight surfactants.
6. The process of Claim 1 wherein said water nanocluster composition is comprised of 10-50% by weight water.
7. (Once amended) The process of Claim 1 wherein said oil formulation is a cosmetic oil formulation.
8. The process of Claim 7 wherein said water nanocluster composition is comprised of:
  - (1) about 5 to 50% by weight water,
  - (2) about 10 to 90% by weight of a cosmetic oil formulation and
  - (3) about 5 to 50% by weight of one or more surfactants selected from the group consisting of fatty acids, ethoxylates and alcohols.



9. (Once amended) The process of Claim 1 wherein said water nanoclusters in said water nanocluster composition are present together with bulk water but constitute the predominant form of water present in said water nanocluster composition.

10. The process of Claim 1 wherein said oil formulation includes pharmaceutical ingredients.

11. (Once amended) A water-in-oil emulsion composition comprised of:

- (1) about 5 to 50% by weight water containing pentagonal dodecahedral water nanoclusters having at least one dimension of less than about 10 nanometers,
- (2) about 10 to 90% by weight of an oil formulation and
- (3) about 5 to 50% by weight of one or more surfactants selected from the group consisting of fatty acids, ethoxylates and alcohols.

15. The composition of Claim 11 wherein said water clusters are in multi-water cluster arrays.

16. (Once amended) The composition of Claim 15 wherein said multi-water cluster arrays are needle-like in form, having at least one dimension less than about 1 nanometer and a second dimension greater than about 3 nanometers

17. (Once amended) The composition of Claim 11 wherein said surfactants are clathrated by said water nanoclusters and extend therefrom resulting in reverse micelles of about 3 nanometers in diameter.

18. (Once amended) The composition of Claim 16 wherein said surfactants are linearly clathrated in the needle cavity resulting in cylindrically symmetric micelles with a large dimension of about 4 nanometers and a small dimension of about 0.8 nanometers.

19. The composition of Claim 11 wherein the composition is in the form of a gel.

20. The composition of Claim 11 wherein the composition is in the form of a cream.
21. The composition of Claim 11 wherein the composition is in the form of a liquid.
22. (Once amended) The composition of Claim 11 wherein the oil formulation is a cosmetic oil formulation selected from the group consisting of soybean, peanut, olive, sesame and paraffin.
23. (Once amended) The composition of Claim 22 wherein said cosmetic oil formulation includes one or more additives selected from the group consisting of nutrients, fragrances and sunscreens, which are soluble in the cosmetic oil formulation.
24. The composition of Claim 11 wherein said oil formulation includes pharmaceutical ingredients.
25. (New) A process for delivery of water nanocluster compositions through the outermost layer of human skin, comprising the steps of:
- preparing a water nanocluster composition comprising water nanoclusters having at least one dimension thereof being between about 0.8 and about 10 nanometers and an oil formulation in the form of a water-in-oil emulsion, and
  - applying said water nanocluster composition onto the outermost layer of human skin.
26. (New) A water-in-oil emulsion composition comprised of:
- (1) about 5 to 50% by weight water containing water nanoclusters having at least one dimension between about 0.8 and about 10 nanometers,
  - (2) about 10 to 90% by weight of an oil formulation and
  - (3) about 5 to 50% by weight of one or more surfactants selected from the group consisting of fatty acids, ethoxylates and alcohols.